

**REMARKS**

New claims 32, 33, 34, 35, 36, 37, 38 and 39 are identical to claims 1, 7, 5, 12, 15, 16, 17, and 18, respectively, of U.S. Patent No. 6,410,010 ("the 010 patent"), titled "Recombinant p53 Adenovirus Compositions," which was issued on June 25, 2002. Applicants hereby copy these claims in order to preserve rights under 35 U.S.C. §135(b).

Support for the new claims can be found throughout the present application. Specifically, support for the terms "recombinant adenovirus which carries an adenovirus vector construct comprising an expression region encoding p53" and "an adenovirus vector construct comprising an expression region encoding p53" can be found, for example, at page 19, lines 4-8. Support for the term "under the control of a cytomegalovirus immediate early promoter" is found, for example, on page 33 lines 4-18. This same section supports the recitation of "an adenovirus vector construct comprising an expression region encoding p53 under the control of a promoter" in claim 35.

Support for the limitation in claim 33 that the region encoding p53 replaces E1A and E1B coding regions is found, for example, at page 13, lines 32-34.

Support for the various recitations to describe the *in vivo* effects of the claimed viruses and constructs can be found throughout the specification and particularly on, *e.g.*, page 40 line 22 to page 42 line 10 and Figures 10A and 10B. This section of the specification demonstrates the *in vivo* efficacy of the invention.

Applicants note that the recitations relating to the effects of the claimed viruses and constructs do not appear to limit the claims because the recitations refer to different aspects of the same phenomenon. Nonetheless, for the sake of completeness, applicants provide the following support for the particular language used to describe the effects of the viruses and constructs. For example, the term "sufficient to inhibit tumor cell growth *in vivo*" is supported at page 28, line 9, which refers to stopping "the uncontrolled growth" of tumor cells in a patient.. The term "sufficient to restore growth suppression to said tumor cell *in vivo*" is supported at page 28, line 4, which refers to use of tumor suppressor genes. The term "sufficient to kill said

tumor cell in vivo" is supported page 28, lines 130-14 which refers to induction of apoptosis in tumor cells.

Applicants do not believe any of the remaining claims of the '010 Patent represent a patentably distinct invention over claims 1, 5, 12, and 15-18 of that patent. Claims 2, 3, 8, and 9 all depend from claim 1 and recite specific levels of p53 introduced by the claimed recombinant adenovirus. Claims 4, 6, 11, and 13 are all dependent claims that recite the use of particular polyadenylation signals, which were well known in the art. Claim 14 depends from claim 8 and adds the limitation that E1A and E1B are deleted. Claim 10 depends from claim 8, but does not appear to add a limitation, since claim 8 depends from claim 1, which requires use of a CMV intermediate early promoter.

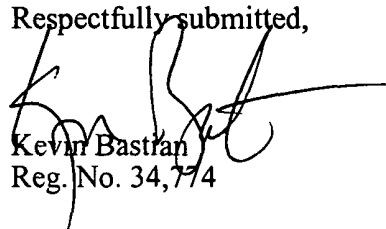
New claims 40 and 41 correspond exactly to two claims that were allowed during the prosecution of the '010 patent, but which did not appear in the issued patent. Support for claims 40 and 41 is found, for example, at page 15, lines 6-10. Claims 40 and 41 correspond exactly to application claims 42 and 57, respectively (*see*, Notice of Allowance, Paper No. 72 in '010 File History). In addition, applicants note that claim 12 of the '010 patent was not among those claims indicated as allowable by the Examiner. In an abundance of caution, applicants have copied this claim in the present application.

Appl. No. Unassigned  
Amdt. dated June 23, 2003  
Preliminary Amendment

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Kevin Bastran', is written over the typed name and registration number.

Kevin Bastran  
Reg. No. 34,774

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8<sup>th</sup> Floor  
San Francisco, California 94111-3834  
Tel: 415-576-0200  
Fax: 415-576-0300  
KLB:cg  
SF 1466691 v1